Alabama Medicaid Agency

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BOB RILEY
Governor

CAROL A. HERRMANN-STECKEL, MPH
Commissioner

September 22, 2006

Dear Pharmaceutical Manufacturer:

This correspondence is to provide you with formal written notification of an upcoming meeting of the Alabama Medicaid Pharmacy & Therapeutics (P&T) Committee, to be held on **Wednesday, November 8, 2006**. This meeting may involve review of one or more of your company's drug products. Please note: this meeting will be held at the Alabama State Capitol Auditorium located in Montgomery, Alabama, and will begin at 9:00 a.m. All meetings of this committee are open to the public.

The following is a list of drug classes and new drugs scheduled for review at this meeting:

Drug Class REVIEWS	
1. Antihistamine Antiemetics — AHFS 562208	7. Inhaled Mast-cell Stabilizers — AHFS 481032
2. Antiemetics, 5-HT_3 Receptor Antagonists — AHFS 562220	8. Orally Inhaled Corticosteroids — AHFS 680400
3. Miscellaneous Antiemetics — AHFS 562292	9. Respiratory Smooth Muscle Relaxants — AHFS 861600
4. Inhaled Antimuscarinics — AHFS 120808	10. Intranasal Corticosteriods — AHFS 520808
5. Respiratory β-Adrenergic Agonists — AHFS 121208	11. Proton-pump Inhibitors — AHFS 562836
6. Leukotriene Modifiers — AHFS 481024	12. Miscellaneous Antidiabetic Agents — AHFS 682092

** Please note that a new drug product must be on the market for a minimum of 6 months from launch date in order to be included in a drug class review.*

New Drug REVIEWS
1. Ranexa® (ranolazine) — AHFS 240492
2. Apidra® (insulin glulisine) — AHFS 682008

As you may be aware, manufacturers whose products are scheduled for review are allowed the opportunity to provide written clinical comments for distribution to the Medicaid P&T Committee members prior to the meeting. For products slated for P&T review, manufacturers are also allowed the opportunity to make brief (no more than 5 minutes) oral summary presentations of product clinical data to the Medicaid P&T Committee on the day of the meeting.

Approval for distribution of written clinical comments to P&T members and approval of oral presentation summary submissions are based strictly upon the following guidelines:

Written Comments:

1) All written comments must be mailed to Medicaid's Clinical Contractor, *MedMetrics Health Partners, Attn: AL Medicaid P&T Support (1-800-644-4079); 100 Century Drive; Worcester, MA 01606*), and received no later than **Wednesday, October 18, 2006**. Packages must be properly labeled "*Attn: AL Medicaid P&T Support*" and include the full contact information of the designated manufacturer's point of contact.
2) Submissions should be limited to one drug product per packet. Manufacturers wishing to provide written comments on more than one drug product must submit a separate packet for each product.

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3) **Submissions are limited to 100 pages single-sided (or 50 pages double-sided) and a maximum binder size of 1 inch.**
4) Written comments should be limited to clinical information only and **must not contain any reference to cost or general drug- or disease-specific economic information.**
5) Written comments must be confined to evidence-based clinical information and not contain anecdotal content.
6) Submissions are limited to hard-copy written form only (not CD-ROM, e-mail, etc.).
7) Manufacturers must provide **twenty (20) copies of written comments** upon submission to *MedMetrics.*

Oral Presentation Summaries:

1) Written notification of your intent to make an oral presentation must be mailed to *MedMetrics Health Partners, Attn: AL Medicaid P&T Support (1-800-644-4079); 100 Century Drive; Worcester, MA 01606*), and received no later than **Wednesday, October 18, 2006**. Submissions must be properly labeled "*Attn: AL Medicaid P&T Support*" and include the full contact information of the designated manufacturer's point of contact.
2) Oral presentation summaries should be limited to one drug product per submission. Manufacturers wishing to provide an oral presentation on more than one drug product must submit a separate one-page summary for each product.
3) Oral presentations must also be limited to clinical information only and **must not contain any reference to cost or general drug- or disease-specific economic information.**
4) Oral presentations must be confined to evidence-based clinical information and not contain anecdotal content.
5) Submissions are limited to hard-copy written form only (not CD-ROM, e-mail, etc.) and should be clearly labeled as "Oral Presentation Summary".
6) **One (1) copy of a one-page summary** of the material to be presented must be received along with the written notification. (Please note: this should be a single-sided document only; do not include references, package inserts, or any other information on the reverse side.)

Failure to abide by all of these requirements upon submission will result in a rejection of the clinical comments and/or oral presentation summaries in their entirety. Manufacturers are also encouraged to submit information as soon as possible. Waiting until just days prior to the deadline for submission of these materials may not allow time for corrections and resubmission prior to the deadline. No submissions or resubmissions will be accepted after the designated deadline.

Please refer to the Medicaid website for additional information related to presentations, timelines, clinical comment submissions, and/or submission of volume discounts. Volume discount submissions should not be included in this submission to MedMetrics, as these will not be reviewed by MedMetrics nor forwarded to Alabama Medicaid. If you should have additional questions regarding this notice or if you have received this letter and are no longer the appropriate contact, please notify the Medicaid Pharmacy Program at (334) 353-4582.

Sincerely,

Bakeba R. Thomas

Bakeba R. Thomas, Administrator
Pharmacy Clinical Support Unit